UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs and Counterclaim-Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD. and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim-Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Judge Joel A. Pisano Magistrate Judge Tonianne J. Bongiovanni

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to the Court's May 11, 2011 Scheduling Order (D.I. 56), as amended July 26, 2011 (D.I. 77), and Local Patent Rule 4.3, Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, "AstraZeneca") and Defendants Hanmi, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively, "Hanmi") hereby provide their Joint Claim Construction and Prehearing Statement for the asserted claims of U.S. Patent Nos. 5,714,504 (the " '504" patent) and 5,877,192 (the " '192" patent).

A. Construction of Terms on Which the Parties Agree

1. '504 Patent Claim Terms

The Parties have agreed to the construction of the below claim terms or phrases in the asserted claims of the '504 patent.

- "**Pure**" (claims 1, 2, 4, 6 and 7) should be construed in accordance with the Court's ruling in *AstraZeneca AB v. Dr. Reddy's Labs., Ltd.*, Claim Construction Order, No. 05-cv-05553-JAP-TJB at D.I. 246, 2010 WL 1981790, at *5–6 (D.N.J. May, 18,

2010) (henceforth, "*AZ v. DRL*"), to mean: *sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation*.

- "**Substantially crystalline form"** (claim 4) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *8, to mean: *sufficient crystallinity present to permit further optical purification of the enantiomer if required*.

2. '192 Patent Claim Terms

The Parties have agreed to the construction of the below claim terms or phrases in the asserted claims of the '192 patent.

- "**Decreased interindividual variation in plasma levels (AUC)**" (claims 1 and 13) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *13, to mean: *a reduced difference or deviation in blood levels of (–)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve*.

- "**Increased average plasma levels (AUC)**" (claims 2 and 14) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *14, to mean: *greater blood levels of (–)-omeprazole, as measured by the area under the concentration-time curve, compared to the typical or usual blood levels for omeprazole, as measured by the area under the concentration-time curve*.

- "**Less pronounced increase in gastrin levels**" (claims 3 and 15) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *15, to mean: *a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole*.

- "**Slow metabolisers**" (claims 3, 4, 15 and 16) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *16, to mean: *individuals among a population that lack one or more drug metabolizing enzymes or express a mutant form of one or more drug metabolizing enzymes (here, the CYP2CI9 enzyme).* [1]

- "**Decreased CYP1A induction**" (claims 4 and 16) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *16–17, to mean: *a reduced production of the drug metabolizing enzyme, CYP1A, in the liver, compared to omeprazole*.

[1] The parties agree that the Court's stated construction of this term in the *AZ v. DRL* reported decision contains an inadvertent error, and that this construction comports with the Court's apparent intent.

- "**An improved antisecretory effect**" (claims 5 and 17) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *17–18, to mean: *an enhanced ability to decrease gastric acid secretion*.

- "**Accelerated rate of healing and accelerated rate of symptom relief**" (claims 6 and 18) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *19, to mean: *a faster resolution of symptoms or effects of a disease, compared to omeprazole*.

- "**Essentially devoid of its (+)-enantiomeric contaminant**" (claim 23) should be construed in accordance with the Court's ruling in *AZ v. DRL*, at *20, to mean: *in at least 99.8% enantiomeric excess (here, (–)-omeprazole).*

B. Each Party's Proposed Construction of Each Disputed Term

The positions of the Parties on the construction of each disputed term in the asserted claims are set forth in Exhibits A and B ('504 patent) and C and D ('192 patent) attached hereto. These Exhibits include an identification of the presently known references from the intrinsic evidence that support each construction, as well as the presently known extrinsic evidence upon which each Party intends to rely to support its proposed construction.

C. Identification of Terms Whose Construction Will Be Most Significant, Case-Dispositive or Substantially Conducive to Promoting Settlement

1. AstraZeneca's Position Regarding the '504 Patent Claim Terms

There is no single term the construction of which will be dispositive of the dispute involving the asserted claims of the '504 patent in its entirety. However, construction of the below terms may be significant to the resolution of this case.

- "**Alkaline salt**" (claims 1, 2, 4, 6 and 7). This term has not been previously construed by the Court. Construction of this term would not be dispositive of the allegations concerning the '504 patent, because if the claims are limited to specific salts as per Hanmi's contentions, Hanmi still infringes under the doctrine of equivalents.

- "**(–)-Enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole**" alone (claims 1, 4, 6 and 7) and as modified by "**optically pure**" (claim 2). AstraZeneca has proposed that these terms be construed in accordance with the Court's earlier ruling *AZ v. DRL*, at *6–8, to

mean: *(–)-omeprazole in at least 94% enantiomeric excess*, and in *at least 98% enantiomeric excess*, respectively. Hanmi has proposed different constructions.

2. Hanmi's Position Regarding the '504 Patent Claim Terms

Hanmi submits that certain claim terms are potentially dispositive.

- "**Alkaline salt**" (claims 1, 2, 4 and 6–7). Hanmi agrees that the construction of the term "alkaline salt," present in each of the asserted claims, will be significant to the resolution of this case. Construction of this term would be dispositive of the allegations concerning the '504 patent, because if the claims are limited to specific salts as per Hanmi's contentions, no asserted claim will be infringed, literally or under the doctrine of equivalents.
- "**(–)-Enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole**" (alone (claims 1, 4, 6 and 7) and as modified by "**optically pure**" (claim 2)). This term is relevant to Hanmi's invalidity contentions and significant to resolution of this case. With due respect for the Court's earlier constructions in *AZ v. DRL* at *6–7, where Hanmi was not a party, Hanmi will show that inclusion of specific numerical limitations is not necessary.

3. AstraZeneca's Position Regarding the '192 Patent Claim Terms

There is no single term the construction of which will be dispositive of the dispute involving the asserted claims of the '192 patent in its entirety. However, construction of the below terms may be significant to the resolution of this case.

- "**Pharmaceutically acceptable salt**" (claims 1–7, 10–19 and 21–23). The Court previously declined to construe this term in *AZ v. DRL*, at *21. Given the nature of Hanmi's contentions, AstraZeneca believes construction of this term is warranted. Construction of this term would not be dispositive of the allegations concerning the '192 patent, because if the claims are limited to specific salts as per Hanmi's contentions, Hanmi still infringes under the doctrine of equivalents.

- "**Consisting essentially of the (–)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole**" (claims 1–7, 10–19, 21 and 22). AstraZeneca has proposed that this term be construed in accordance with the Court's earlier ruling in *AZ v. DRL*, at *9–10, to mean: *(–)-omeprazole in at least 98% enantiomeric excess*. Hanmi has proposed a different construction.

4. Hanmi's Position Regarding the '192 Patent Claim Terms

Hanmi submits that construction of the following terms are significant to resolution of this case and may well be dispositive.

- "**Pharmaceutically acceptable salt**" (claims 1–7, 10–19 and 21–23). Hanmi agrees that the construction of the term "pharmaceutically acceptable salt", present in each of the asserted claims, is a significant issue and may well be dispositive of the allegations concerning the '192 patent, because if the claims are limited to specific salts as per Hanmi's contentions, no asserted claim will be infringed by Hanmi, literally or under the doctrine of equivalents. In the alternative, should such a contention not be adopted, this term should be construed consistently with the new matter presented in the '192 specification, which contains a broader disclosure of acid and alkaline salts.
- As to the terms **"consisting essentially of",** and **"the (–)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole"** (claims 1–7, 10–19, 21–23), as well as their combined usage, Hanmi proposes constructions relevant to invalidity of the asserted claims and which are significant to resolution of this case. With due respect for the Court's earlier constructions s in *AZ v. DRL* at *9-10, where Hanmi was not a party, Hanmi will show that inclusion of specific numerical limitations is not necessary.

D. The Anticipated Length of Time Necessary for the Claim Construction Hearing

AstraZeneca anticipates that a claim construction hearing, including argument and any witness testimony, can be completed in one day or less.

Hanmi anticipates that a claim construction hearing based on argument can be completed in less than one day, but should the Court desire live testimony from what may be multiple expert witnesses, the hearing would take one to two days.

E. Witnesses and their Proposed Opinions and Testimony

To the extent presently known, each witness that any Party proposes to call is identified in Exhibits A, B, C and D attached hereto, along with a summary of each such witness's testimony including, for any expert, each opinion to be offered related to claim construction.

Respectfully submitted,

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